EYE REGISTRATION AND ASTIGMATISM ALIGNMENT CONTROL SYSTEMS AND METHOD

BACKGROUND OF THE INVENTION

Cross-Reference to Related Application

This application is a continuation-in-part of application Ser. No. 09/838,665, filed April 19, 2001, which itself claims priority from and incorporates by reference commonly owned provisional applications Ser. No. 60/198,393, filed April 19, 2000, "Astigmatism Alignment Control Device and Method," and Ser. No. 60/270,071, filed February 20, 2001, "Eye Registration Apparatus and Method."

Field of the Invention

The present invention relates to systems and methods for improving objective measurements preceding corrective eye surgery, and, more particularly, to such systems and methods for improving results of corrective laser surgery on the eye.

Description of Related Art

Laser-in-situ-keratomileusis (LASIK) is a common type of laser vision correction method. It has proven to be an extremely effective outpatient procedure for a wide range of vision correction prescriptions. The use of an excimer laser allows for a high degree of precision and predictability in shaping the cornea of the eye. Prior to the LASIK procedure, measurements of the eye are made to determine the amount of corneal material to be removed from various locations on the corneal surface so that the excimer laser can be

calibrated and guided for providing the corrective prescription previously determined by the measurements. Refractive laser surgery for the correction of astigmatism typically requires that a cylindrical or quasicylindrical ablation profile be applied to the eye. The long axis of this profile must be properly oriented on the eye in order to accurately correct the visual aberration.

An objective measurement of a patient's eye is typically made with the patient sitting in an upright position while focusing on a target image. A wavefront analyzer then objectively determines an appropriate wavefront correction for reshaping the cornea for the orientation of the eye being examined. The LASIK or PRK procedure is then typically performed with the patient in a prone position with the eye looking upward.

It is well known that the eye undergoes movement within the socket comprising translation and rotation ("cyclotorsion") as the patient is moved from the upright measuring position to the prone surgery position. Techniques known in the art for accommodating this movement have included marking the eye by cauterizing reference points on the eye using a cautery instrument (U.S. Pat. No. 4,476,862) or caustic substance, a very uncomfortable procedure for the patient. It is also known to mark a cornea using a plurality of blades (U.S. Pat. No. 4,739,761). The injection of a dye or ink is also used to mark the reference locations to identify the orientation of the eye during measurement, permitting a positioning of the corrective profile to the same orientation prior to surgery. However, the time delay from measurement to surgery often causes the ink to run, affecting the accuracy of an alignment. Making an impression on the eye (U.S. Pat. No. 4,705,035) avoids the caustic effects of cauterizing and the running effect of the ink. However, the impression loses its definition quickly relative to the time period between the measurement and surgery.

For correction of astigmatism, it is known to mark the cornea preparatory to making the surgical incisions (U.S. Pat. No. 5,531,753).

Tracker systems used during the surgical procedure or simply for following eye movement, while the patient is in a defined position, are known to receive eye movement data from a mark on a cornea made using a laser beam prior to surgery (U.S. Pat. No. 4,848,340) or from illuminating and capturing data on a feature in or on the eye, such as a retina or limbus (U.S. Pat. Nos. 5,029,220; 5,098,426; 5,196,873; 5,345,281; 5,485,404; 5,568,208; 5,620,436; 5,638,176; 5,645,550; 5,865,832; 5,892,569; 5,923,399; 5,943,117; 5,966,197; 6,000,799; 6,027,216).

SUMMARY OF THE INVENTION

A system and method are provided for accurately orienting an eye for surgery to the same orientation it had during an objective measurement. An orientation correction algorithm is provided to the software driving a corrective surgical device. Further, pairs of eye images taken at different times can be aligned (registered). The system and method also avoids placing a patient in an uncomfortable or harmful situation.

A first embodiment of the system of the present invention comprises means for performing a first image mapping of an eye of a patient situated in a first position using a predetermined eye feature. Means are further provided for performing a second image mapping of the eye of the patient in a second position different from the first position using the predetermined eye feature. Means are also provided for processing the first and the second image map to determine an edge location of the feature in two dimensions and to locate the predetermined eye feature. Finally, software means are included for calculating

an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position. The procedure may comprise, for example, implementing a correction profile that had been determined with the patient in the first position with, for example, a wavefront analysis and conversion system for calculating an ablation profile for a cornea, such as described in copending and co-owned U.S. Patent Application Serial No. 09/566,668, the disclosure of which is hereby incorporated by reference.

The method of this first embodiment of the present invention is for orienting a corrective program for eye surgery and comprises the steps of performing a first image mapping of an eye of a patient in a first position using a predetermined eye feature. The method also comprises the steps of performing a second image mapping of the eye of the patient in a second position different from the first position using the feature and processing the first and the second image map to determine an edge location of the feature in two dimensions and to locate the feature. Next an orientational change to be applied to a corrective prescription for a surgical procedure to be performed on the eye with the patient in the second position is calculated. The procedure comprises a correction profile determined with the patient in the first position.

Thus this aspect of the present invention provides a system and method for achieving a precise registration of the eye with a measurement of the movement of an eye feature. As a result, the prescription measurement for reshaping the cornea will account for the rotation and translation of the eye occurring between measurements made with the patient in a sitting position and laser surgery with the patient in a prone position.

An additional embodiment of the invention is directed to a system and method for orienting a corrective prescription for eye surgery. In this embodiment a first image map of an eye of a patient is processed at a first time during the surgery to produce a first edge image of the eye in two dimensions, and a second image map of the patient eye is processed at a second time during the surgery to produce a second edge image of the eye in two dimensions.

Two identifiable features are selected from one of the first and the second image maps, a location of the two features in the first and the second edge images is correlated. From the correlated locations is calculated an orientational change to be applied to a previously determined corrective prescription for a correction profile to be achieved on the eye during the surgery. Such a procedure can be carried out on a substantially continuous basis if desired to achieve substantially "real-time" adjustment to the corrective prescription.

Yet another embodiment of the orientation system for eye surgery for correcting astigmatism comprises means for making two alignment marks on an eye of a patient with the patient in a first position. Means are also provided for imaging the eye with the patient in a second position that is different from the first position. The system also comprises a computer that has input and output means. The input means are in electronic connection with the imaging means, and an operator input device is in electronic communication with the computer input means. Means for displaying the eye image to an operator are also in communication with the computer input and output means.

First software means are resident in the computer for superimposing a graphical reticle means onto the eye image on the displaying means and for permitting the graphical reticle means to be moved by the operator under control of the operator input means. The reticle means comprise a line for aligning with the two alignment marks. Second software means also resident in the computer are for calculating an orientational change to be applied to a corrective surgical procedure to be performed on the eye with the patient in the second position. As above, the procedure comprises a correction profile determined with the patient in the first position.

The features that characterize the invention, both as to organization and method of operation, together with further objects and advantages thereof, will be better understood from the following description used in conjunction with the accompanying drawings. It is to be expressly understood that the drawings are for the purpose of illustration and description and are not intended as a definition of the limits of the invention. These and other objects attained, and advantages offered, by the present invention will become more fully apparent as the description that now follows is read in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of the system of a first embodiment of the present invention.

FIG. 2 is a block diagram of the data flow.

FIG. 3 is a view of the original image, before image processing, with feature boxes around the features to be used as registration regions.

FIG. 4 is a view of a Gauss-filtered intensity profile with $\theta_1 = 0$, showing the edge in an *x* direction.

FIG. 5 is a view of a Gauss-filtered intensity profile with $\theta_2 = \pi/2$, showing the edge in a *y* direction.

FIG. 6 is a view of a geometric average of FIGS. 4 and 5.

FIG. 7 is a view with threshold application.

FIG. 8 is a view of the image following application of the thin function.

FIG. 9 is a schematic diagram of the system of a second embodiment of the present invention.

FIG. 10 is a representation of an image of an eye as viewed on a graphical user interface in the second embodiment of the invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

A description of the preferred embodiments of the present invention will now be presented with reference to FIGS. 1–10.

A schematic diagram of a system **10** of a first embodiment of the invention is shown in FIG. 1, data flow and resulting images in FIG. 2, and original and processed images in FIGS. 3–8. A section on the image processing algorithms embodied herein follows the description of the system and method. In an exemplary embodiment of the system **10**, a patient's eye **11** is image mapped in a substantially upright position by capturing a first

video image **12** using a camera such as a charge-coupled-device (CCD) camera **13**. Such an image **12** is illustrated in FIG. 3. The first image **12** is stored in a database **14** in electronic communication with a computer **15** and labeled as an original image from a first measurement.

Next an objective measurement is made on the eye **11** to determine a desired correction profile, using a measurement system **16** such as that disclosed in copending application 09/566,668, although this is not intended as a limitation.

Once the correction profile is determined, the patient is made ready for surgery, and placed in the second position, which is typically prone. Alternatively, the first scan to determine the correction profile may be made in a different location and at a time prior to the surgical procedure, the time interval being, for example, several weeks. Then a second image map **17** is collected using a second camera **18**, in communication with a second system **38** for performing surgery, and these data are also stored in the database **14**. In a preferred embodiment both the first **13** and the second **18** cameras are adapted to collect color images, and these images are then converted using software resident on the computer **15** to intensity profiles **19,20** as grey-scale images. Alternatively, color images may be used. It is useful to collect color images for viewing by the physician, since image mapping of the eye **11** may be made using preselected identifiable images such as blood vessels **21,22** typically seen within the sclera **23**. In a color image, the red color of the vessels **21,22** is clearly identifiable. Typically the second image map **17** is collected during setup prior to surgery using a correction system such as is disclosed in application Serial No. 09/566,668, although this is not intended as a limitation. As the image maps **12,17** are

typically collected with different cameras **13,18**, the qualities of the images **12,17** are expected to be different, making the image processing steps of great importance.

Next the intensity profile **19** of the first video image **12** is processed through a weighting function such as a filter, in a preferred embodiment a Gauss filter, although this is not intended as a limitation. This filter is for eliminating noise within the intensity profiles for defining image edge locations in both an *x* and a *y* orientation to provide two-dimensional information, and also to emphasize or highlight features for subsequent processing. The Gauss filter establishes a first modified intensity profile **24** with $\theta_1 = 0$, as an example, as shown in FIG. 4, an edge view in the *x* direction, the θ values taken relative to the *x* axis. The Gauss filter is again applied to the intensity profiles to establish a second modified intensity profile **25**, with $\theta_2 = \pi/2$, as shown in FIG. 5, an edge view in a *y* direction.

A geometric average of the filtered *x* and *y* orientations is performed and processed to eliminate unwanted noise levels to form a first filtered intensity profile **26** for the first image **12**, yielding a view as shown in FIG. 6. This first filtered intensity profile **26** has been calculated by taking the square root of the sum of the squares of the first **24** and the second **25** modified intensity profiles.

The above process is repeated for the second image **17**, to produce, from the second intensity profile **20**, a third modified intensity profile **27** from application of a Gauss filter with $\theta_3 = 0$ and a fourth modified intensity profile **28**, with $\theta_4 = \pi/2$, and geometric averaging to produce a second filtered intensity profile **29**.

Next an adaptive signal threshold is selected to reduce background noise for the first **26** and the second **29** filtered intensity profiles, resulting in first **30** and second **31** thresholded images, with the first thresholded image **30** shown in FIG. 7. The λ may be different for the first **26** and the second **29** filtered intensity profiles; here $\lambda = 0.03$.

The first **26** and the second **29** filtered intensity profiles **26,29** are then processed through a "thin function" to produce a first **32** and a second **33** edge image, with the first edge image **32** shown in FIG. 8. This step completes the image processing. Next the surgeon selects one or more features in the eye **11**, shown as a first **21** and a second **22** feature (here, blood vessels) in FIG. 3. The selected features are used for correlating between filtered images for the second (surgical) position of the eye **11** with that of the first (measurement) position. Other features may also be used if sufficiently prominent blood vessels are not present. The excimer laser **36** coordinates are then reoriented to accommodate the rotation and translation that took place when moving the patient from a measurement instrument to the surgical device.

The operator proceeds to locate the limbus **34** using a graphical user interface (GUI) while viewing the still image of the eye (FIG. 3). By way of example, a reticle **37** is moved in position to coincide with the limbus **34**. The reticle size may be changed, including a diameter of a circular reticle, or optionally both minor and major radius of an elliptical reticle. The operator then selects a feature or features **21,22** of the eye **11** to be used by outlining the selected feature or features **21,22** within graphical "feature boxes," and the above process is automatically performed by the "push of a button," which takes only seconds to complete in the exemplary embodiment.

Using the first **32** and second **33** edge images, and knowing the center of the reticle **37** (circle or ellipse), the computer **15** determines coordinates for the selected features **21,22**.

Image mapping within each feature **21,22** box is a process of using the transformation described below. By way of example, the process fixes the first edge image **32** and varies the angle of orientation for second edge image **33**.

The computer **15** overlays the first **32** and the second **33** edge image with regard to center and compares each point within the feature **21,22** box. Each edge image **32,33** is also compared for different values of θ to determine maximum matching points. The computer **15** moves the center relation for the edge images **32,33** and seeks to improve its location (center a, b) and value for a θ orientation. Each feature box or area (pixels within area) is processed before moving the center and is completed for every θ (typically $-25° \leq \theta \leq +25°$), which will typically cover a patient's eye rotation when moving from an upright to a prone position. Completing the entire process takes less than 30 sec.

The treatment pattern, typically a laser shot pattern, is thus modified to account for eye rotation resulting from the patient's movement from upright to prone position. In addition, an eye tracking feature of the second system **38** can account for eye movement during surgery independently of the camera **18**.

The system and method for orienting a corrective prescription as described with reference to FIG. 2 may also be applied in "real time" during the corrective surgical procedure, for example, at predetermined intervals. Any additional, usually incremental, cyclotorsion occurring during the procedure can then be detected and compensated for.

This "reorientation" of coordinates is calculated by taking the previously collected image as the "first image" and a newly collected image as the "second image," following the steps as described above. Data for such adjustments can be collected and updated orientational changes calculated substantially continuously throughout the procedure if desired.

By way of further example, code for carrying out the process steps to obtain the image of FIG. 8, and code for carrying out an exemplary embodiment of the above for the steps including the feature coordinate determination through the processing of the feature boxes, are disclosed in provisional application 60/270,071, which is hereby incorporated herein by reference.

The present invention also provides a system and method for aligning (registering) pairs of eye images taken at different times. By way of example, images may be taken at:

1. An undilated pupil at centration time on wavefront system
2. A dilated pupil at measurement time on wavefront system, using multiple measurements
3. A dilated pupil on a surgical system following formation of the flap

To align at least any two images from a mathematics point of view, it is assumed that there is enough information in each of the images to allow for the precise computation of the translational and rotational offsets between pairs of images such that any two images, by way of example, may be overlaid with acceptably small errors. This condition satisfied, an optimized linear transformation between these image pairs is determined. The transformation is uniquely determined by three parameters: a translation vector

$r_0=(a,b)$ (a and b are the x and y coordinates of the translation, respectively) and a rotation angle θ.

Image Processing

The Gauss filter is used to eliminate the noise of both images and is defined as:

$$G(x,y,\sigma_1,\sigma_2) = g(u(x,y),\sigma_1)\cdot g_v'(v(x,y),\sigma_2) \qquad \textbf{1}$$

where

$$g(u,\sigma)=\frac{1}{\sqrt{2\pi\sigma^2}}\exp\left(-\frac{u^2}{2\sigma}\right);\, g_v'(v,\sigma)=-\frac{v}{\sigma}g(v,\sigma) \qquad \textbf{2}$$

and

$$u(x,y)=\cos\theta\cdot x \quad - \quad \sin\theta\cdot y \qquad \textbf{3}$$

$$v(x,y)=\sin\theta\cdot x \quad + \quad \cos\theta\cdot y \qquad \textbf{4}$$

is the rotation of the point (x, y) and θ is the angle of rotation. Here θ is set to be either 0 or π/2, which means the filter will eliminate the noise either in the x direction or the y direction. The standard deviation (σ) determines the shape of the filter.

Let Im(x,y) represent the image data function. Applying the Gauss filter to the image function is equivalent to making the convolution of these two functions.

$$NewIm(x,y) = Im(x,y)*G(x,y,\sigma_1,\sigma_2) \qquad \textbf{5}$$

Next the threshold ξ is computed.

$$\xi = \lambda \cdot \max |\, NewIm(x,y) \,| + (1-\lambda) \cdot \min |\, NewIm(x,y) \,| \qquad \mathbf{6}$$

where $0<\lambda<1$. The threshold to the new image file is applied as

$$\operatorname{Im} N(x,y) = \begin{cases} |\, New \operatorname{Im}(x,y)| & if \quad |New \operatorname{Im}(x,y)| > \xi \\ \xi & otherwise \end{cases} \qquad \mathbf{7}$$

A bilinear interpolation method is used to determine the edge point, the following comprising a thin function:

$$P = (1-\alpha)\left[(1-\beta)P_0 \;+\; \beta P_2\right] \;+\; \alpha\left[(1-\beta)P_1 \;+\; \beta P_3\right] \qquad \mathbf{8}$$

where gradient vector

$$\textit{gradient of } \operatorname{Im}(x,y) = (\alpha,\beta) \qquad \mathbf{9}$$

and P_i are points in a neighborhood of (x,y).

Image Mapping

After processing both images, the best parameters in this linear transformation should be found. The “best” means that, in a given parameter space, it is desired to find a point (parameters) in that space, such that under these parameters the linear transformation minimizes the error between those pairs of images.

The linear transformation is defined as:

$$\begin{pmatrix} x' \\ y' \end{pmatrix} = \begin{pmatrix} \cos\theta & -\sin\theta \\ \sin\theta & \cos\theta \end{pmatrix} \begin{pmatrix} x - center_x \\ y - center_y \end{pmatrix} + \begin{pmatrix} a \\ b \end{pmatrix} \qquad \mathbf{10}$$

The criterion to find the best transform parameters is to minimize the error:

$$\min_{(a,b,\theta)\in D} \sum_{(x,y)} |\operatorname{Im} N_{prior}(x,y) - \operatorname{Im} N_{post}(x',y')| \qquad \mathbf{11}$$

The pair (*center*$_x$, *center*$_y$) is the coordinate of the center point of the limbus from one image.

$$D = \{(a,b,\theta) \mid a_1 < a < a_2, \quad b_1 < b < b_2, \quad \theta_1 < \theta < \theta_2\} \qquad \mathbf{12}$$

is the parameter (searching) space. The problem is to determine the center-point coordinate (*center*$_x$, *center*$_y$) and the searching space $\{a_1, a_2, b_1, b_2, \theta_1, \theta_2\}$. The limbus is manually located in this embodiment on both images to obtain the center coordinate (*center*$_x$, *center*$_y$) from the measurement system, and the center coordinate (*center*$_{xx}$, *center*$_{yy}$) from the surgical system. The search region is defined as

$$a_1 = center_{xx} - k, \qquad a_2 = center_{xx} + k \qquad \mathbf{13}$$

$$b_1 = center_{yy} - k, \qquad b_2 = center_{yy} + k \qquad \mathbf{14}$$

where k is a integer. The searching resolution is $\Delta\theta = 0.5°$, and the search range is ±25°; so $\theta_1 = -25°$, $\theta_2 = +25°$. The summation $\sum$ is taken over a reference area $(x,y) \in \Omega$. The reference area is manually located to satisfy the assumption mentioned above.

A second embodiment of the present invention includes an orientation system **40** for eye surgery for correcting at least astigmatism, which is shown schematically in FIG. 9. The graphical user interface and elements thereof are illustrated in FIG. 10. A means for making two alignment marks **41,42** on an eye **43** of a patient (FIG. 10) with the patient in a first position may comprise, for example, an ink pen **44**, although this is not intended

as a limitation, and alternative marking means known in the art may also be used. In current use, the first position typically comprises a seated upright position. In a preferred embodiment, the alignment marks **41,42** are made at the "3 o'clock" and "9 o'clock" positions to the eye's sclera **45** just outside the margin of the limbus **46**. In other words, the alignment marks **41,42** are made at approximately the $\pi/2$ and $3\pi/2$ radial positions relative to the limbus **46**, with a 0 radial position comprising a top point of the limbus **46**. Thus the alignment marks **41,42** are made substantially collinear with a diameter of the limbus **46**. One of skill in the art will recognize that these values are exemplary only, and that other locations can be used with similar results.

A camera, preferably a color video camera **47**, is provided for imaging the eye with the patient in a second position different from the first position. Typically the second position comprises a prone position.

The system **40** (FIG. 9) also comprises a computer **48** that has input and output means. One input **49** is in electronic connection with the camera **47**. Means are also in communication with the computer's input and output means for displaying the eye image to an operator via, for example, a graphical user interface (FIG. 10). Display hardware may comprise, for example, a color video display monitor **50**. An operator input device, which may comprise, for example, a mouse **51**, is also in electronic communication with another input **52** to the computer **48**. Alternatively, other operator input devices may be contemplated; for example, the monitor **50** may comprise a touch screen.

In a preferred embodiment, a corrective system **53** to be used in performing surgery, for example, laser ablation surgery on the cornea, comprises an eye tracker **54** as known

in the art. In this embodiment, the monitor **50** displays both a tracked eye image **55** and an untracked eye image **56** (FIG. 10).

A first software routine **57** is resident in the computer **48** for routing the eye images to the monitor **50** and also for superimposing a graphical reticle **58** onto the tracked eye image **55**. The first software routine **57** further permits the graphical reticle **58** to be moved by the operator under control of the mouse **51**. The graphical reticle **58** comprises a circle **59** for superimposing on the eye's limbus **46** and a cross-hair including a pair of perpendicular lines **60,61**, both of which are substantially diametric with the circle **59**. Typically the generally horizontal line **60** is used to align with the alignment marks **41,42** on the eye **43**. In a color system, the graphical reticle **58** comprises a color for contrasting with the eye **43**, such as, but not limited to, yellow.

The monitor **50** preferably is adapted to display a graphical user interface **62** (FIG. 10) that has an interactive control sector **63** thereon. It will be understood by one of skill in the art that this graphical user interface is exemplary only, and that any number of such interfaces may be envisioned so long as the ability to align reticles is provided.

As shown in the exemplary screen of FIG. 10, the control sector **63** comprises a plurality of control sectors, in the form of "buttons," the activation of which moves the graphical reticle **58** in a desired direction. Here the buttons comprise two for horizontal movement, "left" **64** and "right" **65**, two for vertical movement, "up" **66** and "down" **67**, and two for rotation, counterclockwise **68** and clockwise **69**. Clicking on these buttons **64-69** with the mouse **51** causes motion of the graphical reticle **58** on the interface **62** in the

indicated direction, as mediated by the first software routine **57** (see rotated graphical reticle in FIG. 10).

In addition, a button **72** performs recentering of the lines **60,61** over the cornea.

A second software routine **71** is also resident in the computer **48** for calculating an orientational change to be applied to a corrective surgical procedure. The procedure, also resident in the computer **48**, is to be performed on the eye **43** with the patient in the second position. Such a procedure may comprise, for example, an ablation correction profile that had been determined by a measurement system **71** in electronic communication with the computer **48**, with the patient in the first position.

It will be understood based on the teachings of the present invention that in addition to images viewed on the surface of the eye, the position of the retina and any movement thereof may be determined using the above methods to view images on the retina. By way of example, the video camera may be replaced by a scanning laser ophthalmoscope, as disclosed in U.S. Pat. No. 6,186,628 to Van de Velde, which disclosure is hereby incorporated by reference; a retinal nerve fiber layer analyzer, as disclosed in U.S. Pat. No. 5,303,709 to Dreher et al., which disclosure is hereby incorporated by reference; or a fundus camera to provide images of blood vessel patterns that can be used in the same manner as scleral blood vessels as herein described.

In the foregoing description, certain terms have been used for brevity, clarity, and understanding, but no unnecessary limitations are to be implied therefrom beyond the requirements of the prior art, because such words are used for description purposes herein and are intended to be broadly construed. Moreover, the embodiments of the apparatus

illustrated and described herein are by way of example, and the scope of the invention is not limited to the exact details of construction.